

REMARKS

Reconsideration of the present application is respectfully requested in light of the foregoing amendments and following remarks. Claims 1-24 are pending. Claims 1, 7, and 8 have been amended for clarification purposes only and without acquiescing to any rejection. Applicant expressly reserves the right to pursue prosecution of any presently excluded subject matter or claim embodiments in one or more future continuation, continuation-in-part and/or divisional application(s). Support for the amendments may be found throughout the specification and claims as originally filed. No new matter has been added to the application.

Application Informalities

As an initial matter, Applicant thanks the Examiner for entering Applicant's election of claims 1-21 in response to the restriction requirement of August 30, 2005. Applicant further thanks the Examiner for noting the typographical error in claim 1, and notes that this error has now been corrected.

Rejection under 35 U.S.C. § 112, First Paragraph

Claims 1-21 stand rejected under 35 U.S.C. § 112, first paragraph, as allegedly lacking enablement. Applicant thanks the Examiner for noting that the specification is enabling for photodynamic therapy for the reduction of adipose tissue with photosensitizing agent, Npe6, its conjugated form, and monoclonal antibody. However, the Action alleges the specification does not provide enablement for Npe6 prodrugs or other photosensitizing agents or prodrugs without undue experimentation. More specifically, the Action alleges the specification fails to provide experimental examples as to how the photosensitizing agents of claims 8 and 9 are effective in reduction of adipose tissue.

Applicant respectfully traverses this rejection and submits the application as filed is fully enabled for the scope of the claims. As an initial matter, Applicant notes that working examples of every embodiment of an invention are *not required* to satisfy the enablement requirement of 35 U.S.C. §112, first paragraph. (See MPEP § 2164.02, first paragraph: "Compliance with the enablement requirement of 35 U.S.C. § 112, first paragraph, does not turn

on whether an example is disclosed.”) Indeed, the invention does not actually have to be reduced to practice prior to filing. *See Gould v. Quigg*, 822 F.2d 1074, 1078, 3 USPQ 2d 1302, 1304 (Fed. Cir. 1987). Applicant submits that despite this, multiple working examples are provided in the application as filed, thus exceeding the enablement requirement.

Applicant also notes that an application as filed is presumed to be enabling, and the Patent Office has the initial burden of establishing a reasonable basis to question the enablement provided in the disclosure. *See In re Wright*, 999 F.2d 1557, 1562, 27 USPQ 2d 1510, 1513 (Fed. Cir. 1993). Applicant submits that the application as filed provides adequate teachings for the manner and process of practicing the invention, and the Action fails to carry its burden of establishing a reasonable basis, with appropriate explanation and supporting evidence, as to why there is any doubt regarding the accuracy of statements made in the disclosure of the application. Without such explanation and supporting evidence, “there would be no need for the applicant to go to the trouble and expense of supporting his presumptively accurate disclosure.” *See In re Marzocchi*, 439 F.2d 220, 224, 169 USPQ 367, 370 (CCPQ 1971).

Furthermore, Applicant submits that photosensitizing agents or photo-activatable drugs in general are known in the art for treating diseases, such as cancer and macular degeneration. *See*, for example, U.S. Patent Nos. 4,675,338 and 4,693,885, both of which are incorporated by reference in the present application as filed. Thus, the general knowledge of one of skill in the art is high and would allow the skilled artisan to have a reasonable expectation of success in using any agent of the present application rather than merely the specific agent disclosed in the working examples.

Applicant notes that there is no documentary evidence presented by the Action that calls into question the ability to utilize other photosensitive compounds. In fact, the skilled artisan would conclude that photactivatable drugs of a variety of types are readily available and may be utilized in the compositions and methods of the presently claimed invention without undue experimentation.

Applicant submits that while one of skill in the art may have to perform routine experimentation to optimize conditions with specific circumstances, this type of routine experimentation is not considered “undue.” In light of these factors, Applicant submits the

application as filed satisfies the enablement requirement of 35 U.S.C. § 112, first paragraph, in that one of skill in the art would be able to practice the full scope of the invention without undue experimentation.

Nonetheless, without acquiescing to this rejection, Applicant submits that claims 1 and 8 have been amended for clarification. Accordingly, Applicant submits this rejection has been overcome and respectfully requests that it be withdrawn.

Rejection under 35 U.S.C. § 103(a)

Claims 1-21 stand rejected under 35 U.S.C. § 103(a) as allegedly being unpatentable over Paolini et al. (U.S. Pat. No. 5,954,710) in view of Chen et al. (U.S. Pat. No. 5,445,608) and further in view of Bommer et al. (4,693,885) and Sato et al. (*Poultry Sci.*, 78: 1286-1291, 1999). The Action alleges that Paolini et al. teach a device and methods for eliminating adipose layers by means of laser energy, while Chen et al. allegedly teach a method and apparatus for light-activated therapy; Bommer et al. allegedly show that Npe6 is a known photosensitizing agent for phototherapy; and Sato et al. allegedly teach lipoprotein lipase monoclonal antibodies are known to reduce adipose tissue in chicken, but concedes Sato et al. do not teach the combination of using the antibodies with a photosensitizing agent.

Applicant respectfully traverses this rejection and submits that none of the claimed references, alone or in combination, render the presently claimed invention obvious, nor has the Action set forth a *prima facie* case of obviousness. As a first point, Applicant submits Paolini et al. teach piercing through the skin with a needle in order to deliver a laser beam to the underlying adipose tissue but, as conceded in the Action, do not teach the use of a photosensitizing agent for photodynamic therapy. The Action alleges that Chen et al. teach a method of photodynamic treatment at a site in a patient's body. Applicant notes, however, that Chen et al. teach an implantable light source for internal treatment, and do not disclose the presently claimed invention of a photodynamic therapy for the reduction of adipose tissue or adipocytes in a mammalian subject.

Further, Bommer et al. and Sato et al. do not remedy the deficiencies of Paolini et al. and Chen et al., either alone or in combination, as Bommer et al. merely disclose Npe6 is a photosensitizing agent, and Sato et al. teach an unrelated mechanism for reducing fat in poultry.

Applicant respectfully submits the Action has failed to demonstrate a *prima facie* case of obviousness. Applicant submits that the Action states, "Clearly, one of skilled (sic) in the art would have assumed the photodynamic therapy method of Chen et al. combined with the method of Paolini et al. would produce the applicant's instant invention is (sic) the absence of evidence to the contrary." (See page 6, Office Action dated January 17, 2006). However, Applicant respectfully submits that this is not the proper test for determining obviousness of an invention. The law is well established that a rejection for obviousness which depends on a combination of cited references must provide some teaching, suggestion, or motivation to combine the references. *In re Rouffet*, 149 F.3d 1350, 1355 (Fed. Cir. 1998).

Applicant submits that Paolini et al. merely disclose a laser scalpel that is irrelevant to the presently claimed invention, while Chen et al. disclose the general notion of using an LED for photodynamic therapy and Bommer et al. teach Npe6 may be used as a photodynamic therapy agent. Applicant submits the cited references, either alone or in combination, fail to teach every element of the presently claimed invention, including a method for photodynamic therapy for the reduction of adipose tissue or adipocytes in a mammalian subject comprising: administering to the subject a therapeutically effective amount of a photosensitizing agent or a photosensitizing agent delivery system, wherein said photosensitizing agent or said photosensitizing agent delivery system selectively localizes in the adipose tissue or the adipocytes; irradiating at least a portion of the subject with light at a wavelength absorbed by said photosensitizing agent, wherein said light is provided by a light source; and wherein said irradiation is administered at a relatively low fluence rate that results in the activation of said photosensitizing agent; and wherein said PDT drug is cleared from the skin and subcutaneous tissues of the subject prior to said irradiation. (Emphasis added.)

Applicant submits not only do the cited references fail to teach each element of the presently claimed invention, but the Action fails to point to any motivation or suggestion that

would lead a skilled artisan to arrive at the presently claimed invention in light of the cited references.

Additionally, it is improper to use hindsight to select references that contain specific elements of the present invention, in order to attempt to establish a case of obviousness. *Id.* Instead, the Action must “show reasons that the skilled artisan, confronted with the same problems as the inventor and with no knowledge of the claimed invention, would select the elements from the cited prior art references for combination in the manner claimed.” *Id.* 149 F.3d at 1358. Since no such teaching, suggestion, or motivation to combine the cited references is set forth by the Action, and no reasons are offered that would indicate a skilled artisan would select the elements from the cited references without the impermissible use of hindsight, as well as add the missing elements, the Action has failed to establish a *prima facie* case of obviousness. Accordingly, Applicant submits this rejection has been overcome and respectfully requests that it be withdrawn.

Application No. 10/687,579
Reply to Office Action dated January 17, 2006

The Director is authorized to charge any additional fees due by way of this Amendment, or credit any overpayment, to our Deposit Account No. 19-1090. All of the claims remaining in the application are now believed to be allowable. Favorable consideration and a Notice of Allowance are earnestly solicited.

Respectfully submitted,

SEED Intellectual Property Law Group PLLC

A handwritten signature in black ink, appearing to read 'William T. Christiansen', written over a horizontal line.

William T. Christiansen, Ph.D.
Registration No. 44,614

WTC:hh

Enclosure:
Postcard

701 Fifth Avenue, Suite 6300
Seattle, Washington 98104-7092
Phone: (206) 622-4900
Fax: (206) 682-6031

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